

STERILE WATER- water injection
General Injectables & Vaccines, Inc

Sterile Water For Injection, USP Single Dose Vial

Description

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. For I.V. injection, add sufficient solute to make an approximately isotonic solution.

Water for Injection, USP is chemically designated H₂O. The glass vial is Type I or II borosilicate glass and meets the requirements of the powdered glass test according to the USP standards.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper labeled volume.

Clinical Pharmacology

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water for distribution depends primarily on the concentrations of electrolytes in the body compartments and sodium (Na⁺) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP when used only as a pharmaceutical aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in neonates or very small infants.

Indications and Usage

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

Contraindications

Sterile Water for Injection, USP must be made approximately isotonic prior to use.

Warnings

Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.

Precautions

Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture.

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.

Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy Category C. Animal reproduction studies have not been conducted with Sterile Water for injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection with additives should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness have been established in pediatric patients. However, in neonates for very small infants the volume of fluid may affect fluid and electrolyte balance.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers. Discard unused portion.

Adverse Reactions

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patients, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

Overdosage

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriated corrective measures. See **WARNINGS, PRECAUTIONS** and **ADVERSE REACTIONS**.

Dosage and Administration

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Sterile Water for Injection, USP is supplied in the following:

Unit of Sale	Total Content
NDC 0409-4887-05 Tray of 25 Glass Fliptop Vials	1 mL
NDC 0409-4887-10 Tray of 25 Plastic Fliptop Vials	10 mL
NDC 0409-4887-34 Tray of 30 Plastic Fliptop Vials	10 mL
NDC 0409-4887-20 Tray of 25 Plastic Fliptop Vials	20 mL
NDC 0409-4887-50 Tray of 25 Plastic Fliptop Vials	50 mL
NDC 0409-4887-99 Case of 25 Glass Fliptop Vials	100 mL

Store at 20 to 25C (68 to 77F). [See USP Controlled Room Temperature.]

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1292-1.0

Revised: 05/2018

Sample Package Label

NDC # 52584 - 887 - 10
ITEM# :2580622
LOT # XXXXXXXXX
EXP : mm - dd - yy

Packaged By
General Injectables and Vaccines, Inc
80 Summit View Lane
Bastian, VA 24314

STERILE WATER

10 mL

INJECTION, USP
SINGLE-DOSE

**SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION**

**FOR DRUG DILUENT USE.
USE ASEPTIC TECHNIQUE.
Contains no antimicrobial or other added
substance.
Sterile, nonpyrogenic.
Use only if clear and seal is intact and
undamaged. Do not give intravenously
unless rendered nearly isotonic. Use
promptly; discard unused portion.**

**Keep out of children's reach.
Store at 20 to 25C (68 to 77F). (See USP
Controlled Room Temperature.)**



MANUFACTURER INFORMATION
Mfr: Hospira
ORIG MFG LOT: XX - XXX - XX
NDC:0409 - 4887 - 10

(10)XXXXXX
(17)XXXXXXXX
(01)XXXXXXXXXXXX
(21)XXXXXXXXXXXX
RX ONLY

NDC # 52684 - 887 - 20
ITEM# :2585070
LOT # XXXXXXXXX
EXP : mm - dd - yy

Packaged By
General Injectables and Vaccines, Inc
80 Summit View Lane
Bastian, VA 24314

STERILE WATER

20 mL

INJECTION, USP
SINGLE DOSE

SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION

FOR DRUG DILUENT USE. CONTAINS NO ANTIMICROBIAL
OR OTHER ADDED SUBSTANCE. STERILE, NONPYROGENIC.
DO NOT GIVE INTRAVENOUSLY UNLESS RENDERED NEARLY
ISOTONIC. USE ASEPTIC TECHNIQUE. USE ONLY IF
CLEAR AND SEAL IS INTACT AND UNDAMAGED. USE
PROMPTLY; DISCARD UNUSED PORTION.

Keep out of children's reach.

Store at controlled room
temperature 68F to 77F.

MANUFACTURER INFORMATION

Mfr: Hospira

ORIG MFG LOT: XX - XXX - XX

NDC:0409 - 4887 - 20



(10)XXXXXX
(17)XXXXXXXX
(01)XXXXXXXXXXXX
(21)XXXXXXXXXXXX
RX ONLY

NDC # 52584 - 887 - 50
 ITEM# :1819911
 LOT # XXXXXXXXX
 EXP : mm - dd - yy

Packaged By
 General Injectables and Vaccines, Inc
 80 Summit View Lane
 Bastian, VA 24314

STERILE WATER
 INJECTION, USP
 SINGLE DOSE
 50 mL

SEE MANUFACTURER'S INSERT
 FOR COMPLETE PRODUCT AND
 PRESCRIBING INFORMATION

FOR DRUG DILUENT USE. DO NOT GIVE INTRAVENOUSLY
 UNLESS RENDERED NEARLY ISOTONIC. USE PROMPTLY.
 CONTAINS NO ANTIMICROBIAL OR OTHER ADDED SUBSTANCE
 USE ONLY IF CLEAR AND SEAL IS INTACT AND UNDAMAGED
 USE ASEPTIC TECHNIQUE. DISCARD UNUSED PORTION.
 STERILE, NONPYROGENIC.

Keep out of children's reach.

Store at controlled room
 temperature 68F to 77F.



MANUFACTURER INFORMATION
 Mfr: Hospira
 ORIG MFG LOT: XX - XXX - XX
 NDC:0409 - 4887 - 50

(10)XXXXXX
 (17)XXXXXXXXXX
 (01)XXXXXXXXXXXXXX
 (21)XXXXXXXXXXXXXX
 RX ONLY

STERILE WATER

water injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52584-887(NDC:0409-4887)
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Water (UNII: 059QF0K00R) (Water - UNII:059QF0K00R)	Water	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:52584-887-10	1 in 1 BAG	07/20/2016	
1		10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:52584-887-20	1 in 1 BAG	07/20/2016	
2		20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
3	NDC:52584-887-50	1 in 1 BAG	07/20/2016	
3		50 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
4	NDC:52584-887-99	1 in 1 BAG	07/20/2016	01/18/2017
4		100 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018801	03/01/2010	

Labeler - General Injectables & Vaccines, Inc (108250663)

Revised: 8/2021

General Injectables & Vaccines, Inc